4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-0957]

Compliance Policy Guide Sec. 397.100 Accuracy Requirements for Indication of Temporal-Maximum Ultrasonic Power; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of the compliance policy guide (CPG) Sec. 397.100 Accuracy Requirements for Indication of Temporal-Maximum Ultrasonic Power. The Agency is taking this action because the CPG identified in this notice contains policies that have been superseded by a subsequent FDA action.

DATES: The withdrawal is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993-0002, 301-796-6353.

SUPPLEMENTARY INFORMATION: We are announcing the withdrawal of the CPG entitled "Compliance Policy Guide Sec. 397.100 Accuracy Requirements for Indication of Temporal-Maximum Ultrasonic Power, 21 CFR 1050.10(c)(1)(ii)." On January 20, 2023, FDA issued a final rule entitled "Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser, and Ultrasonic Products" (88 FR 3638). The final rule repealed 21 CFR 1050.10, which includes performance standards for ultrasonic therapy products. Therefore, the policies in CPG Sec. 397.100 are no longer applicable, and this CPG is being withdrawn.

Dated: February 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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